IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

HUNTINGTON DIVISION

EMPLOYER TEAMSTERS-LOCAL NOS. 175/505 HEALTH AND WELFARE TRUST FUND; and INTERNATIONAL BROTHERHOOD OF TEAMSTERS-VOLUNTARY EMPLOYEE BENEFITS TRUST,

Plaintiffs,

v. CIVIL ACTION NO. 3:12-0587

BRISTOL MYERS SQUIBB COMPANY; SANOFI-AVENTIS U.S., L.L.C.; and SANOFI-AVENTIS U.S., INC.,

Defendants.

MEMORANDUM OPINION AND ORDER

Pending before the Court is Defendants' motion (ECF No. 50) to dismiss Plaintiffs' Second Amended Complaint ("SAC"). The parties presented oral argument regarding the motion to dismiss on January 16, 2013, in Huntington. For the reasons stated below, the Court **GRANTS** the motion to dismiss (ECF No. 50). Also pending before the Court is Plaintiffs' motion for leave to file a supplemental memorandum (ECF No. 70). For reasons appearing to the Court, the Court **GRANTS** this motion (ECF No. 70).[1]

Statement of Facts

The drug at the center of this litigation—Plavix (clopidogrel bisulfate)—is a prescription anticoagulant, or blood thinner. The Food & Drug Administration ("FDA") initially approved

[1] The Court has reviewed Plaintiffs' proposed supplemental memorandum, attached to their motion, and this supplemental memorandum did not alter the Court's analysis.

Plavix for use in patients who experienced a recent heart attack, stroke, or peripheral arterial disease ("PAD"), and later additionally approved its use in patients suffering from acute coronary syndrome ("ACS"). Mem. in Supp. of Defs.' Mot. to Dismiss SAC, at 3-4, ECF No. 51. Bristol Myers Squibb manufactured Plavix, and together with Sanofi engaged in massive marketing of the drug. Plavix has generated massive revenues, with allegedly over $42 billion in sales worldwide, and is one of the world's top-selling drugs. SAC ¶ 3, ECF No. 48.

The Employer Teamsters-Local Nos. 175/505 Health and Welfare Trust Fund and International Brotherhood of Teamsters Voluntary Employee Benefits Trust ("Plaintiffs") commenced this action against Defendants Bristol Myers Squibb Company ("BMS"), Sanofi-Aventis U.S., L.L.C., and Sanofi-Aventis U.S., Inc.[2] on February 27, 2012. Compl., ECF No. 1. The Complaint alleged that Defendants engaged in misleading and false marketing of Plavix, resulting in Defendants' unjust enrichment.

Plaintiffs properly filed their First Amended Complaint ("FAC") on April 6, 2012, adding a claim for breach of implied warranty of merchantability in addition to unjust enrichment. ECF No. 13. Defendants moved for dismissal of the FAC, and that motion became ripe for disposition on July 9, 2012. The Court scheduled oral argument concerning the motion to dismiss for October 12, 2012, but then canceled oral argument because Plaintiffs indicated that they wanted to amend their pleadings.

Plaintiffs timely moved on October 18, 2012, for leave to file a second amended complaint due to recent legal developments, namely, a recently unsealed complaint filed in the Southern District of Illinois. *See U.S. v. Bristol Myers Squibb*, No. 11-cv-246-DRH-SCW (S.D.

[2] Additional defendants were named in the initial Complaint, but those additional defendants were subsequently terminated from the litigation, leaving the three defendants noted.

Ill.). The Court granted such leave, and Plaintiffs filed the SAC on October 24, 2012. ECF No. 48. As with the FAC, the SAC alleges unjust enrichment and breach of implied warranty of merchantability. The SAC differs from the FAC in many regards, however, such as: the attachment of multiple exhibits, whereas the FAC had none; the inclusion of more substantive details; reference to the recently unsealed complaint; and a re-wording of the breach of implied warranty claim.

Plaintiffs allege that Defendants misrepresented Plavix as being more effective than aspirin for certain indicated usages, namely treating patients who recently experienced myocardial infarction ("MI") or stroke. Specifically, Plaintiffs claim that Defendants mischaracterized scientific studies as supporting these efficacy claims, when in fact such studies do not actually show Plavix's superiority. Plaintiffs allege that the marketing campaign surrounding Plavix influenced doctors' decisions in prescribing the drug. While each Plavix pill costs approximately $4.00, an equivalent dose of aspirin costs approximately $0.04. Given this price difference and Plavix's lack of superiority over aspirin, Plaintiffs—as third party payors ("TPPs")—allege that they suffered damages by reimbursing Plavix prescriptions on behalf of their insureds. Plaintiffs allege that the monetary benefit retained by Defendants constitutes unjust enrichment. Plaintiffs further claim that Defendants have breached the implied warranty of merchantability. Specifically, Plaintiffs allege that "Plavix was not fit for its ordinary and intended pharmacological purpose of being a superior alternative to aspirin for certain indicated usages" and that "Defendants therefore breached the warranty implied by law that Plavix was fit for the ordinary purposes for which it was to be used." SAC ¶¶ 58-59.

Defendants have moved for dismissal of the SAC. ECF Nos. 50, 51. They argue that there are significant independent intervening events between the Plavix marketing and the prescription reimbursements, and that proximate causation is therefore lacking. Additionally, Defendants argue that Plaintiffs have not suffered any economic injury from paying for Plavix prescriptions because premiums cover the Plavix reimbursement costs, and insurance funds take into account the risk of wrongful prescriptions when setting premiums. Lastly, Defendants argue that Plaintiffs' claims sound in fraud and must therefore meet the pleading standard of Federal Rule of Civil Procedure 9(b), which such claims fail to do.

Defendants' motion to dismiss the SAC became ripe for disposition on December 3, 2012.[3] The parties presented oral argument on January 16, 2013, in Huntington. Therefore, the Court is ready to resolve this motion to dismiss.

In Section I, the Court discusses generally the requirements of Rule 12(b)(6). Next, in Section II, the Court examines whether Plaintiffs plausibly state a claim for relief based on the elements of each claim, apart from any causation requirement; specifically, Section II discusses how Plaintiffs characterize Plavix's ordinary purpose, and Plaintiffs' pleading of unjust enrichment. Lastly, in Section III, the Court analyzes Plaintiffs' pleading of causation.

I. Standard Of Review under Rule 12(b)(6)

[3] Defendants filed a Renewed Motion for Transfer of Actions Pursuant to 28 U.S.C. § 1407 for Coordinated or Consolidated Pretrial Proceedings with the U.S. Judicial Panel on Multidistrict Litigation ("JPML") on October 15, 2012. Defendants subsequently moved for this Court to stay decision on the motion to dismiss, pending the JPML's decision on the motion to transfer. ECF No. 55. Additionally, Defendants have filed multiple notices supporting the motion to stay. ECF Nos. 58, 60, 63. For reasons presented at oral argument, the Court has decided to resolve the motion to dismiss regardless.

In *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), the United States Supreme Court disavowed the "no set of facts" language found in *Conley v. Gibson*, 355 U.S. 41 (1957), which was long used to evaluate complaints subject to 12(b)(6) motions. 550 U.S. at 563. In its place, courts must now look for "plausibility" in the complaint. This standard requires a plaintiff to set forth the "grounds" for an "entitle[ment] to relief" that is more than mere "labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id*. at 555 (internal quotation marks and citations omitted). Accepting the factual allegations in the complaint as true (even when doubtful), the allegations "must be enough to raise a right to relief above the speculative level . . . ." *Id*. (citations omitted). If the allegations in the complaint, assuming their truth, do "not raise a claim of entitlement to relief, this basic deficiency should . . . be exposed at the point of minimum expenditure of time and money by the parties and the court." *Id*. at 558 (internal quotation marks and citations omitted).

In *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), the Supreme Court explained the requirements of Rule 8 and the "plausibility standard" in more detail. In *Iqbal*, the Supreme Court reiterated that Rule 8 does not demand "detailed factual allegations[.]" 556 U.S. at 678 (internal quotation marks and citations omitted). However, a mere "unadorned, the-defendant-unlawfully-harmed-me accusation" is insufficient. *Id*. "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Id*. (quoting *Twombly*, 550 U.S. at 570). Facial plausibility exists when a claim contains "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id*. (citation omitted). The Supreme Court continued by explaining that, although factual allegations in a complaint must be accepted as true for purposes of a motion to

dismiss, this tenet does not apply to legal conclusions. *Id.* "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id*. (citation omitted). Whether a plausible claim is stated in a complaint requires a court to conduct a context-specific analysis, drawing upon the court's own judicial experience and common sense. *Id*. at 679. If the court finds from its analysis that "the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged-but it has not 'show[n]'-'that the pleader is entitled to relief.'" *Id*. (quoting, in part, Fed. R. Civ. P. 8(a)(2)). The Supreme Court further articulated that "a court considering a motion to dismiss can choose to begin by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth. While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations." *Id*. This Court will keep the requirements of Rule 12(b)(6) in mind as it examines Plaintiffs' claims.

II. Pleading of Ordinary Purpose and Unjust Enrichment

Plaintiffs allege that Defendants are liable for breach of implied warranty of merchantability and unjust enrichment because Plavix was not as effective as claimed. Specifically, Plaintiffs raise the following allegations:

> 1. Defendants lied about the safety and efficacy of Plavix . . . . Specifically, Defendants misrepresented the purported health benefits of Plavix by promoting it as a superior drug to aspirin for certain indicated usages for which Plavix is actually no more effective than aspirin, then charging approximately 100 times more for Plavix than aspirin costs.
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> 4. Defendants have achieved these enormous sales by unlawfully misleading physicians, consumers and health insurers regarding the efficacy and safety of Plavix . . . . Defendants promote Plavix as being more effective than aspirin . . . .
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> 5. Defendants' wrongful promotion of Plavix as more effective than aspirin caused Plaintiffs to suffer significant damages. Plavix costs approximately $4.00

per pill, whereas an equivalent dose of aspirin costs approximately $0.04 per pill, despite the fact that Plavix actually is no more effective than aspirin for many of its indicated usages.

15. Defendants implemented a multi-faceted scheme to wrongfully overcharge Plaintiffs by unjustly and deceptively promoting Plavix as superior to aspirin in order to increase Plavix sales.

26. . . . [B]ased on the CAPRIE study,[4] it would be incorrect and improper to claim that Plavix is more effective than aspirin at reducing the risk of negative heart health outcomes for patients who had recently suffered an ischemic stroke.

31. . . . Defendants falsely represented that the CAPRIE study concluded that Plavix was more effective than aspirin for . . . these subgroups.

38. . . . Defendants misleadingly characterized the PRoFESS study[5] results in communications with physicians to enforce the unsupported notion that Aggrenox was inferior to Plavix . . . .

40. Defendants' purpose of presenting the results of the PRoFESS study in this confusing manner was to increase the Plavix market share in the post-stroke population, despite study results indicating that Plavix simply is not more effective than Aggrenox or aspirin for such patients.

46. Defendants used traditional drug marketing tactics to reach prescribing physicians. Sales representatives targeted and talked to physicians, nurses and other health care providers, including those located in West Virginia, about Plavix. As described above, those communications were deliberately misleading at Defendants' instruction.

50. On information and belief, these marketing efforts, unjustly misleading though they were, were effective and resulted in physicians prescribing Plavix and causing health insurers, including Plaintiffs, to reimburse the cost of their

[4] The 1996 Clopidogrel [Plavix] vs. Aspirin in Patients at Risk for Ischemic Events ("CAPRIE") study compared the efficacy of Plavix and aspirin in reducing cardiovascular risks. The study found Plavix to be more effective than aspirin in reducing the risk of negative heart health outcomes for PAD patients, but not more effective than aspirin for recent MI patients and individuals who recently experienced ischemic stroke. SAC ¶¶ 25-27 (footnote not in original).

[5] The 2008 Prevention Regimen for Effectively Avoiding Second Strokes ("PRoFESS") study examined the efficacy of Plavix and prescription drug Aggrenox (aspirin plus dipyridamole) in preventing secondary stroke for recent stroke patients. The results did not show that Plavix was more effective that Aggrenox. SAC ¶¶ 36-37 (footnote not in original).

> insureds' Plavix prescriptions, even though Plavix was, in fact, no better than . . . aspirin for many patients.
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> 52. Defendants deliberately provided incorrect information to physicians, the consuming public, and health insurers including Plaintiffs regarding the efficacy of Plavix compared to the cheaper alternative of aspirin. Defendants manipulated, misrepresented, and failed to disclose adverse clinical data to those parties in order to turn a profit by inducing health insurers, including Plaintiffs, to pay for Plavix.
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> 58. At the time of these Plavix purchases, and at the time Plaintiffs paid for them through insurance reimbursements, Plavix was not fit for its ordinary and intended pharmacological purpose of being a superior alternative to aspirin for certain indicated usages.

SAC.

As mentioned earlier, Plaintiffs' SAC re-words the claim for breach of implied warranty of merchantability as it appeared in the FAC. In the SAC, Plaintiffs allege that "Plavix was not fit for its *ordinary and intended pharmacological purpose of being a superior alternative to aspirin* for certain indicated usages" and that "Defendants therefore breached the warranty implied by law that Plavix was fit for the *ordinary purposes* for which it was to be used." ¶¶ 58-59 (emphasis added). In comparison, the FAC alleged that "at the time of the purchases Plavix did not have the quality that a buyer would reasonably expect" and "at the time of these purchases, Defendants knew that Plavix was *not of the quality to safely and effectively treat certain conditions Defendants claimed it would be safe and effective [for treating] and was not fit for the ordinary purposes for which Plavix was to be used*." ¶¶ 46-47 (emphasis added). In other words, while the FAC alleges that Plavix had the ordinary purpose of "safely and effectively treat[ing] certain conditions," the SAC instead recasts Plavix as having the ordinary purpose of "being a superior alternative to aspirin for certain indicated usages."

West Virginia statutory law details the requirements of the implied warranty of merchantability:

> (2) Goods to be merchantable must be at least such as
> (a) pass without objection in the trade under the contract description; and
> (b) in the case of fungible goods, are of fair average quality within the description; and
> (c) are *fit for the ordinary purposes for which such goods are used*; and
> (d) run, within the variations permitted by the agreement, of even kind, quality and quantity within each unit and among all units involved; and
> (e) are adequately contained, packaged, and labeled as the agreement may require; and
> (f) *conform to the promises or affirmations of fact made on the container or label if any*.

W. Va. Code § 46-2-314 (emphasis added). This statute is based on the Uniform Commercial Code. *See* U.C.C. § 2-314. The implied warranty is created by operation of law, and is not premised on a seller's promises or representations beyond identifying the ordinary purpose of the product.

Plavix's ordinary purpose is to act as an anticoagulant. The FDA approved Plavix for its blood-thinning properties in treating patients who experienced a recent heart attack, stroke, PAD, or ACS. There is no indication that the FDA approval was related to Plavix's efficacy compared to aspirin and other alternatives. Also, this Court has reviewed the Plavix labeling information,

and has found nothing on that label suggesting that Plavix's ordinary purpose was to act as a superior alternative to aspirin or Aggrenox.[6]

Plaintiffs do not allege that Plavix was not fit for its ordinary purpose of being an anticoagulant. Rather, Plaintiffs allege that Plavix was not better than alternatives such as aspirin and Aggrenox. Under the U.C.C., claims about a product's superiority over another product are not part of the implied warranty of merchantability. RICHARD A. LORD, 18 WILLISTON ON CONTRACTS § 52:76 (4th ed. 2012) (footnotes omitted) ("As a general principle . . . the implied warranty of merchantability requires only that the goods be fit for their ordinary purpose, not that they be perfect or in perfect condition, or be outstanding or superior, or of the best or highest quality."); *see also Sessa v. Riegle*, 427 F. Supp. 760, 769 (E.D. Pa. 1977), *aff'd*, 568 F.2d 770 (3d Cir. 1978) ("The standard established [by U.C.C. § 2-314] does not require that goods be outstanding or superior."); *Miller v. Badgley*, 753 P.2d 530, 535 (Wash. Ct. App. 1988) ("In order to be merchantable, goods need not be outstanding or superior . . . ."). Furthermore, "a product that performs its ordinary functions adequately does not breach the warranty merely because it does not function as well as the buyer would like . . . ." 18 WILLISTON ON CONTRACTS § 52:76 (footnote omitted).

[6] Plaintiffs included Plavix labeling information, issued in February 2011, with their SAC. ECF No. 48-4. Also, Defendants attach Plavix labeling information, dated March 2010, to their motion to dismiss. ECF No. 50-2. The Court may properly take into account all such labeling when considering a motion to dismiss. *See Van Matre v. Boilermaker-Blacksmith Nat'l Pension Trust*, No. 3:10-cv-1291, 2011 WL 3684816, at *3 n.1 (S.D. W. Va. Aug. 23, 2011) (quoting *Witthohn v. Fed. Ins. Co.*, 164 Fed. App'x 395, 396 (4th Cir. 2006)) ("'[A] court may consider official public records, documents central to plaintiff's claim, and documents sufficiently referred to in the complaint so long as the authenticity of these documents is not disputed' without converting a motion to dismiss into one for summary judgment").

Iqbal and *Twombly* require that a cause of action be supported by factual allegations sufficient to make the claim plausible. The factual allegations in the SAC concern affirmative conduct by Defendants amounting to an express warranty[7]—that Plavix was superior to aspirin—and do not suggest that Plavix was unfit or ineffective for its prescribed uses. Because of Plaintiffs' mischaracterization of Plavix's ordinary purpose, Plaintiffs have failed to state a claim for breach of implied warranty of merchantability, and this is sufficient grounds for dismissing that claim.

Next the Court turns to Plaintiffs' unjust enrichment claim. The elements of an unjust enrichment claim are: "(1) a benefit conferred upon the [defendant], (2) an appreciation or knowledge by the defendant of such benefit, and (3) the acceptance or retention by the defendant of the benefit under such circumstances as to make it inequitable for the defendant to retain the benefit without payment of its value." *Veolia Es Special Servs., Inc. v. Techsol Chem. Co.*, No. 3:07-cv-0153, 2007 WL 4255280, at * 9 (S.D. W. Va. Nov. 30, 2007) (citing 26 WILLISTON ON CONTRACTS § 68:5 (4th ed.)). West Virginia specifically requires that the benefits were "received and retained under such circumstance that it would be inequitable and unconscionable to permit the party receiving them to avoid payment therefor." *See Realmark Devs., Inc. v. Ranson*, 542

[7] *See* W. Va. Code, § 46-2-313:

> (1) Express warranties by the seller are created as follows:
> (a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.
> (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.

Though a claim for breach of implied warranty of fitness for a particular purpose may also theoretically be possible, Plaintiffs have not presented this claim either. *See* W. Va. Code, § 46-2-315.

S.E.2d 880, 884-85 (W. Va. 2000) (citing *Copley v. Mingo Cnty. Bd. of Educ.*, 466 S.E.2d 139 (W. Va. 1995)).

The Court notes that at least one state allows unjust enrichment claims to be dismissed when the underlying tort claim has also been dismissed. *See, e.g., In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, No. 3:09-MD-02100-DRH, 2010 WL 3119499, at *9 (S.D. Ill. Aug. 5, 2010) (citing *Allegheny Gen. Hosp. v. Philip Morris, Inc.*, 228 F.3d 429 (3d Cir. 2000)) (dismissing unjust enrichment claim, under Pennsylvania law, when fraud or misrepresentation claim had been dismissed). West Virginia law has no such requirement, and so the Court's dismissal of the breach of implied warranty claim would not alone provide a sufficient basis for dismissing the unjust enrichment claim.

The Court nonetheless dismisses Plaintiffs' unjust enrichment claim because, as with their claim for breach of implied warranty of merchantability, Plaintiffs have not pled unjust enrichment with sufficient plausibility to pass muster under *Iqbal* and *Twombly*. The SAC alleges that Defendants misrepresented Plavix's efficacy, Defendants "caused physicians to prescribe Plavix to patients insured by Plaintiffs," and that "Plaintiffs paid Defendants for these Plavix prescriptions"—a benefit which Defendants have retained. ¶¶ 52-54. Plaintiffs also point to Plavix's high cost compared to aspirin. However, the SAC does not allege, let alone plausibly, whether any prescriptions were written based on a misunderstanding of Plavix's efficacy. Nor does it allege how Defendants' retention of payments for a product that was effective in its ordinary purpose—though perhaps not as effective compared to other drugs as claimed—rises to the level of constituting unjust enrichment.

In summary, the Court dismisses both of Plaintiffs' causes of action for failure to state a plausible claim.

III. Pleading of Causation

Even if Plaintiffs had sufficiently alleged that Plavix failed to fulfill its ordinary purpose and that Defendants' retention of payments for Plavix—a drug which fulfilled its ordinary purpose as an anticoagulant—constituted unjust enrichment, both claims would still be dismissed for failure to sufficiently plead proximate causation.

Defendants claim that the causation between the alleged marketing activities and the reimbursement of Plavix prescriptions is riddled with too many intervening events for the Court to impose liability on Defendants. In support of their motion to dismiss, Defendants point to *Pennsylvania Employees Benefit Trust Fund v. AstraZeneca Pharmaceuticals LP*, No. 6:09-cv-5003-Orl-22DAB, 2009 WL 2231686 (M.D. Fla. July 20, 2009). In that case, a health and welfare trust fund sued AstraZeneca for breach of express warranty and unjust enrichment, based on AstraZeneca's alleged misleading and false marketing of the drug Seroquel. The district court held that reliance was a required element of the express warranty claim, and would have dismissed on those grounds alone. *See id.* at *4 ("[T]he third party recipient of an express warranty must be aware of the *specific terms* of the warranty in order to sustain a claim for breach of that warranty. Thus, Plaintiff cannot simply rely on the prescription pads of physicians or claims for reimbursement from pharmacies as a means by which express warranties were conveyed.").

That district court separately concluded, however, that the complaint also failed to allege proximate causation, as distinct from reliance. In doing so, that court relied on its own earlier

discussion of proximate cause in *Ironworkers Local Union No. 68 v. AstraZeneca Pharmaceuticals LP*, 585 F. Supp. 2d 1339 (M.D. Fla. 2008), *aff'd on other grounds*, 634 F.3d 1352 (11th Cir. 2011). Specifically, the district court stated that "[t]hough this Court's opinion in *Ironworkers* examined the issue of proximate cause primarily in the context of Plaintiffs' federal RICO claims, the reasoning underlying that opinion applies with equal force to the state claims presented in this case." *Pa. Emps. Benefit Trust Fund*, 2009 WL 2231686, at *5 (footnote omitted). The court then noted that "physicians use their independent medical judgment to decide whether Seroquel is the best treatment for a given patient," and "[this] independent judgment can be influenced by a number of things, only one of which may be representation by a manufacturer as to a particular drug's relative safety and efficacy." *Id.*, 2009 WL 2231686, at *5 (quoting *Ironworkers*, 585 F. Supp. 2d at 1344). The court then dismissed for lack of proximate causation.

The district court decision in *Ironworkers*, affirmed on other grounds by the court of appeals,[8] examined class action RICO claims brought against AstraZeneca for false marketing of Seroquel. In that case, the district court applied the Supreme Court's "direct relation" standard of proximate causation, found in *Holmes v. Securities Investor Protection Corporation*, 503 U.S.

[8] The court of appeals affirmed *Ironworkers* not based on lack of causation, but rather on the basis that TPPs "take into account all known risks that might cause [them] to pay for medically unnecessary or inappropriate prescriptions" when they set their premiums, thus ensuring that premiums cover costs regardless of whether prescriptions end up being given for inappropriate reasons. 634 F.3d at 1368. When insurers decided to reimburse patients for prescriptions of a given drug, "the insurers assumed the risk of paying for all prescriptions of drugs covered by their policies, including medically unnecessary or inappropriate prescriptions—even those caused by fraudulent marketing." *Id*. at 1364. Neither *Ironworkers* opinion, however, is binding on this Court, and this Court finds the causation reasoning used by the district court in *Ironworkers* to be more persuasive than the court of appeal's argument about economic injury.

258 (1992).[9] Under that standard, proximate causation required "some direct relation between the injury asserted and the injurious conduct alleged." *Ironworkers*, 585 F. Supp. 2d at 1344 (quoting *Holmes*, 503 U.S. at 268). The district court found proximate causation lacking for the RICO claims based on that standard and the standard's three underlying policies.[10] *Id.* at 1344-45. Furthermore, the district court applied similar reasoning to the state law claims for consumer protection violations, common law fraud, and negligent misrepresentation, dismissing all of those claims for lack of proximate causation. *Id.* at 1345-46.

Another district court has applied the *Holmes* "direct relation" proximate causation standard, this time to misleading marketing claims against Bayer for its advertising of the contraceptive drug YAZ. *In re Yasmin*, 2010 WL 3119499 (S.D. Ill. Aug. 5, 2010). That district court, relying on *Holmes*, dismissed the plaintiffs' civil RICO claims, and additionally dismissed the plaintiffs' common law negligence and misrepresentation claims. *Id.*, 2010 WL 3119499, at *7-9 (noting that "the proximate cause analysis for Plaintiffs' common law actions mirrors the

[9] The Supreme Court's discussion of proximate causation in *Holmes* provides a general formula, not just applicable to RICO claims. *See Holmes*, 503 U.S. at 268-69.

[10] Those three policies, or factors, are as follows:

> First, the less direct an injury is, the more difficult it becomes to ascertain the amount of a plaintiff's damages attributable to the violation, as distinct from other, independent, factors. Second, quite apart from problems of proving factual causation, recognizing claims of the indirectly injured would force courts to adopt complicated rules apportioning damages among plaintiffs removed at different levels of injury from the violative acts, to obviate the risk of multiple recoveries. And, finally, the need to grapple with these problems is simply unjustified by the general interest in deterring injurious conduct, since directly injured victims can generally be counted on to vindicate the law as private attorneys general, without any of the problems attendant upon suits by plaintiffs injured more remotely.

Holmes, 503 U.S. at 269-70 (citations omitted). The Supreme Court mentions that these policies underlie Clayton Act causation, and "apply with equal force" to RICO claims. *Id.* at 269. This Court likewise finds these policies to be persuasive in the causation analysis generally.

direct proximate cause analysis applicable in civil RICO actions").

The Third Circuit Court of Appeals examined causation, and found it lacking, in *In Re Shering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235 (3d Cir. 2012). In that case, patients and TPPs sought damages as a result of defendant pharmaceutical company's alleged illegal marketing of certain oncology and Hepatitis drugs for off-label use. Specifically, the TPP claims were in connection with two Rebetol prescriptions. The court of appeals noted that the TPP "has not established that its alleged injury is fairly traceable to [defendant] Schering's alleged wrongful conduct," and therefore "the Complaint was properly dismissed for lack of Article III standing." *Id.* at 246. The TPP had argued that Shering falsely marketed other drugs, Schering was the sole marketer of Rebetol, and therefore Shering's misconduct in marketing Rebetol could be inferred. The Third Circuit rejected this reasoning, explaining that "[i]t is pure conjecture to conclude that because Schering's misconduct caused other doctors to write prescriptions for ineffective off-label uses for other products, [TPP] Local 331 ended up paying for two prescriptions for Rebetol due to the same kind of misconduct." *Id.* at 248.

These situations are distinguishable from that presented in *In re Neurontin Marketing & Sales Practices Litigation*, where the District Court of Massachusetts entered judgment in favor of Plaintiffs Kaiser Foundation Health Plan and Kaiser Foundation Hospitals on their claim against Pfizer under California's Unfair Competition Law, in relation to Pfizer's marketing of the drug Neurontin. No. 04-CV-10739-PBS, 2011 WL 3852254 (D. Mass. Aug. 31, 2011). In support of this judgment, the court noted that defendants had made misrepresentations about Neurontin directly to and concealed information directly from Kaiser's Drug Information Service ("DIS"), which is responsible for researching drugs and forwarding drug information to the

committees that ultimately decide what drugs to approve for prescription by doctors. *Id.* at *56.[11] These direct communications included defendants' responses to DIS questions about proper drug usage. *Id.* at *29. This helped establish the causation necessary for Plaintiffs to succeed on their claim.

The courts in the above cases all engaged in necessary line-drawing to limit the permissible scope of recovery when an alleged injury involves a potentially complex chain of causation with many intervening events. The Supreme Court of Appeals of West Virginia engaged in similar line drawing in *White v. Wyeth,* 705 S.E.2d 828 (W. Va. 2010), where individuals who purchased and used certain hormone replacement therapy drugs sought damages from drug manufacturer Wyeth and an advertising agency. The plaintiffs alleged that the defendants engaged in unfair and deceptive advertising and marketing practices, in violation of the West Virginia Consumer Credit and Protection Act ("WVCCPA"). In the course of answering a certified question about the pleading of reliance under the WVCCPA, the court examined the nature of the acts alleged. Specifically, "when consumers allege that a purchase was made because of an express or affirmative misrepresentation, the causal connection between the deceptive conduct and the loss would necessarily include proof of reliance on those overt representations." *Id.* at 837 (citations omitted). In contrast, "[w]here concealment, suppression or omission is alleged, and proving reliance is an impossibility, the causal connection between the

[11] The district court examined misrepresentation and concealment in the context of assessing reliance, which is a required element under California's Unfair Competition Law. Although reliance is not necessarily required in the instant case, *In re Neurontin*'s discussion of specific direct communications with Kaiser provides an illustrative contrast to the cases above where causation was found lacking.

deceptive act and the ascertainable loss is established by presentation of facts showing that the deceptive conduct was the proximate cause of the loss." *Id.* at 837.

In the end, however, the court found that the statutory consumer action at issue, West Virginia Code Section 46A-6-106(a), and the WVCCPA generally, did not apply to private causes of action related to prescription drugs. *Id.* 837-38. This is because doctors, rather than consumers, select which drugs to prescribe to an individual, and consumers are thereby protected by the doctor's medical judgment. *Id.* (citations omitted). *White* examines a cause of action under the WVCCPA, which has its own statutory purposes, as distinct from the causes of action in the instant case. Therefore, although Plaintiffs' allegations characterize Defendants' wrongful conduct as the types of affirmative acts which would require reliance under *White*, this Court hesitates to find that Plaintiffs must prove reliance in the present case.[12] Nonetheless, *White* has some application here, and can guide this Court's analysis of proximate causation and line-drawing.

In summary, *Holmes* and the other cases above suggest that the proximate causation analysis is about carefully drawing a line so as to distinguish the direct consequences in a close causal chain from more attenuated effects influenced by too many intervening causes. Based on the foregoing, this Court is persuaded that the proximate causation analysis for both of Plaintiffs' claims should be similar to that utilized in claims for consumer fraud and RICO, as well as other

[12] Plaintiffs concede they did not allege reliance other than in a conclusory fashion, if at all. It is not clear if reliance must be pled in express warranty claims under West Virginia law. *See Michael v. Wyeth, LLC*, No. 2:04-cv-0435, 2011 WL 2150112, at *8 (S.D. W. Va. May 25, 2011) (noting open question of whether reliance is required, and "anticipat[ing] that West Virginia's high court would follow the rebuttable presumption approach" to the issue of reliance, meaning that reliance need not be proven). Resolution of whether reliance is required is unnecessary, however, because of the sufficient grounds that otherwise exist for dismissal of both claims.

state law claims, as outlined above. Although the cases discussed involve various causes of action, they all use the same guiding principles in assessing proximate causation, and this Court is guided by those same principles in the instant case. The Court finds that Plaintiffs' claims do not satisfy the "direct relation" test found in *Holmes* and affirmed by the district court in *Ironworkers*, and also finds that the policies announced in *Holmes* weigh in favor of dismissal here. Between Defendants' alleged misleading marketing and Plaintiffs' prescription reimbursements lies a vast array of intervening events, including the "independent medical judgment" of doctors. *Ironworkers*, 585 F. Supp. 2d at 1344. Without any specific allegations as to who received these misrepresentations, how the misrepresentations influenced doctors, and why certain patients received Plavix instead of alternative medications, this Court is left without sufficient allegations from which to properly infer that proximate causation is satisfied. Therefore, both of Plaintiffs' claims should be dismissed for lack of causation.

Because the Court has found other grounds which provide sufficient justification for dismissing both of Plaintiffs' claims, the Court need not reach the issue of whether Plaintiffs' claims sound in fraud and, if so, whether Plaintiffs' claims satisfy the higher pleading standard mandated under Federal Rule of Civil Procedure 9(b). Similarly, this Court summarily rejects, without having to reach, Defendants' economic-injury-in-fact argument grounded in the court of appeals' *Ironworkers* decision for the reasons stated earlier. This Court likewise need not discuss application of the passing-on defense.

Conclusion

For the reasons stated above, the Court **GRANTS** Defendants' motion to dismiss (ECF No. 50), and **DISMISSES** Plaintiffs' Second Amended Complaint (ECF No. 48) in its entirety.

The Court also **GRANTS** Plaintiffs' motion for leave to file a supplemental memorandum (ECF No. 70), and has considered the proposed supplemental memorandum.

The Court **DIRECTS** the Clerk to send a copy of this written Opinion and Order to counsel of record and any unrepresented parties.

ENTER: January 29, 2013

ROBERT C. CHAMBERS, CHIEF JUDGE